K122206

510k Summary

As required by 21 CFR 807.92 (c)

MAR 2 1 2013

1- Date summary prepared: March 19, 2013

2- Owner/submitter/applicant/sponsor information:

GARAVENTA (CANADA) LTD
7505 134A Street, Surrey BC, Canada V3W 7B3
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3- Submission official correspondent:

Jay Mansour
Mansour Consulting LLC
845 Aronson Lake Court. Roswell, GA 30075 USA
678-908-8180
Fax 678-623-3765

4- Device information:

Common/usual/classification name: ELEVATOR, WHEELCHAIR

Device name: Garaventa X3 inclined platform lift.

Device classification:

FDA 3 letter code	PCE
FDA regulation number: 21 CFR:	890.3930
Regulation medical specialty	Physical Medicine
Review panel	Physical Medicine
Class	2

5- Substantial equivalency is claimed against the following predicate device(s):

510k number	Trade or Proprietary or Model Name	Manufacturer
K981486	STAIR-LIFT (Models GSL-1, GSL-2 & GSL-3)	GARAVENTA (CANADA) LTD

6- Description of the device:

The Garaventa X3 inclined platform lift is intended to mechanically transport one person in a wheelchair or in a fold down seat equipped with a seat belt, up and down stairs in a private or public facility either indoors or outdoors, on straight stairways.

The Garaventa X3 inclined platform lift uses two custom-cut extruded aluminum guide rails to guide and support the platform. An upper rail houses the drive rack that is engaged by the pinion gear providing platform movement as well as acting as the raceway for the control wiring. A lower rail stabilizes the platform keeping it in a level traveling position. The Garaventa X3 inclined platform lift has steel guide rails and haul ropes or cables are used for those products instead of extruded aluminum.
The Garaventa X3 inclined platform lift does not require a special cabinet to house the drive system. The drive system of the Garaventa X3 inclined platform lift is an on-board rack and pinion drive system. The drive system is protected from accidental contact by the user by a conveyance "hard" cover.

The Garaventa X3 inclined platform lift is a computer-controlled device equipped with a microprocessor and the software resides inside the conveyance controller.

The safety network monitors several switches, landing cam, the battery voltage and motor current limits. These are independent of the microprocessor system and provide a positive electro-mechanical means to reliably and safely stop the lift in any possible hazardous situation.

The controller is located in the conveyance unit. It receives the operating commands from the call station or from the conveyance controller. The conveyance control module always has a priority over the call stations.

The conveyance controller is powered by 24V DC batteries that are attached to the conveyance. The conveyance controller also controls the "barrier arms" motor, platform side-load motor and the platform motor in either of the landings.
The status of the safety switches and the emergency stop button are monitored by the conveyance controller.

There is a call station located at each landing. The call station transmits commands using a wireless simplex channel while the conveyance continuously scans all RF signals (decoded) from both call stations.

Call stations allow the user to call and send the unit into the desired landing and also fold and unfold the platform. The call stations are linked with the conveyance through the wireless link. The system uses a 2.4 GHz ISM band using encoded pulse for each call station. The call station does not process the button / command but simply transfers the state of each button to the conveyance.

The Garaventa X3 inclined platform lift is provided in four models: one fully automatic, two semi automatic, and one fully manual.

7- Intended use:

The Garaventa X3 inclined platform lift is a motorized lift device intended for medical purposes to provide a means for a disabled person to move a wheelchair from one level to another

8- Indications for use:

The Garaventa X3 inclined platform lift is indicated to mechanically transport one person in a wheelchair or in a fold-down seat up and down stairs in a private or public facility either indoors or outdoors.

9- Basis for a determination of substantial equivalency:

(a) Indications for use:

The indications for use are the same as the predicate device(s).

(b) Technological characteristics:

The main differences between this device and predicate device are:

i. X3 uses battery only in the control system.
ii. X3 uses remote control call station using specified frequency.

The table below reflects how the change in design is controlled and tested against, providing the basis of the determination of substantial equivalency in a summarized format.

#	Subject	Main design item/feature change	Reason of change	Test conducted
1	Rail System	X3 Uses the Rail System of GSL2, not the tube system of GSL 1/3.	Ease in production and installation of the product.	Use existing GSL 2 Rail System for straight lifts applications. Tested with "X3 Safety Circuit Test" attached in this report in tab J Item 26 to comply with ASME 18.1-2008 and CSA B335-09.
2	Hanger System	X3 uses the Hanger of GSL 1/3, not the bulky Hanger of GSL 2.	Ease in production and installation of the product.	Use the existing hanger of GSL 1 & 3 for complete control system. Safety tests done and documented in "X3 Safety Circuit Test" attached in this report in Tab J Item 26 to comply with ASME 18.1-2008 and CSA B335-09.
3	Platform System	X3 uses the Platform of GSL 1/3, not the GSL 2 Platform.	Align control system with the hanger system	Use the existing platform of GSL 1 & 3 for conveyance system. Safety tests done and documented in "X3 Safety Circuit Test" attached in this report in Tab J Item 26 to comply with ASME 18.1-2008 and CSA B335-09.
4	Call Station	Remote Control Call Station with specified frequency.	Ease in control and portability of call station. Cost-effective.	Remote control Call station designed for wireless operation to improve the wired operations of GSL 2 and GSL 1 & 3 for portability and ease of operation. Allocated band frequency has no conflict with outside radio frequencies. Design compliance to ASME 18.1 – 2008 and CSA B 335-09.
5	Power Source	The whole control system is by battery only.	Cost-effectiveness and ease in installation.	Instead of using the Main AC power of 120 V, X3 uses battery only to minimize power consumption and ease in installations. Design compliance to ASME 18.1 – 2008 and CSA B 335-09.

(c) Non clinical tests- brief discussion: *Tests on functionality and safeties has been done in the design phase in accordance to applicable standards*. See Tab J3 Item 26 : Test Report X3 Safety Circuit.

(d) Clinical tests- brief discussion: Not applicable

(e) Non clinical and clinical tests- conclusions drawn demonstrating that the device is as safe and as effective, and performs as well as or better than the predicate device(s): As shown in the safety tests and functionality of the equipment, X3 performs effectively as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 21, 2013

Garaventa (Canada) Ltd.
% Jay Mansour, MSQA, BE, RAC, LA
Mansour Consulting
845 Aronson Lake Court
Roswell, GA 30075

Re: K122206
Trade/Device Name: Garaventa X3 Inclined Platform Lift
Regulation Number: 21 CFR 890.3930
Regulation Name: Wheelchair elevator
Regulatory Class: Class II
Product Code: PCE
Dated: February 11, 2013
Received: February 22, 2013

Dear Mr. Jay Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

We note that your device exceeded the Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 CFR Part 890.9), and therefore required the submission and clearance of a premarket notification prior to commercial distribution in the United States. Future devices of this same type, that meet the exemption criteria and do not exceed the limitations of exemptions found in 21 CFR Part 890.9, will be exempt from the premarket notification requirements of the Act.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122206

Device Name: Garaventa X3 inclined platform lift

Indications For Use:

The Garaventa X3 inclined platform lift is intended to mechanically transport one person in a wheelchair or in a fold-down seat up and down stairs in a private or public facility either indoors or outdoors.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Brian D. Pullin -S

(Division Sign-off)
Division of Neurological and
Physical Medicine Device
510(k) Number K122206